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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Eric Abel

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EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT

PAPER NUMBER

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/561,649	<b>Applicant(s)</b> ABEL ET AL.	
	<b>Examiner</b> LINDSEY BACHMAN	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 18-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 18-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

This Office Action is in response to Applicant's amendment filed 7 April 2010.

### ***Response to Arguments***

Applicant argues that the 112 rejection to Claim 6 should be withdrawn because the claim was amended to clearly associate the term "the stressed position" with the collapsed position. No such amendment was made and as such, the rejection is maintained.

Applicant argues that the amendment to independent claims 1 and 34 overcomes Shaw'572 because Shaw'572 does not teach a guide member with an aperture defining an access area that is at least partially spaced from the leading end. Further, Applicant argues that the expansion arms do not extend across edges of the aperture, as claimed. However, an access area is provided between 1, 1', and 1" and element 11 is part of element 2 in the cited embodiment of Figure 4a, 4b and as such, arms extend across edges of the access area.

Regarding Applicant's argument that Shaw'572 does not provide access to the body anywhere except through the distal end of tube 11 because Shaw'572 does not disclose using accessing the body through openings in stays 1, 1', and 1". However, regarding device claim 1, this argument regards the intended use of the device. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of

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performing the intended use, then it meets the claim. Regarding the method claim 34, the claim only require that at least a portion of the access area is spaced from leading end of the apparatus and does not require that the body is accessed through the particular portion of the access area that is spaced from the leading edge of the apparatus.

Regarding Claim 20, Applicant argues that the stays do not provide access around at least half the perimeter of the guide member because the stays are provided at 90 degree intervals. Examiner disagrees since when in the expanded configuration, the stays are spread from the perimeter of the guide tube and provide access over at least half of the perimeter.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14, 18-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claim 1 and 34, there is lack of antecedent basis for the term “edge regions” in the claim. Further, it is not clear what Applicant means by edge regions, as this term is not defined by the specification.

Claim 6 recites “the stressed position” in line 3, and it is unclear whether this refers to the collapse position or the expansion position, as both as recited as being stressed positions previously in the claim.

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: that the expansion arms are constructed out of a shape memory alloy. To overcome this rejection, Examiner recommends making Claim 25 depend from Claim 24.

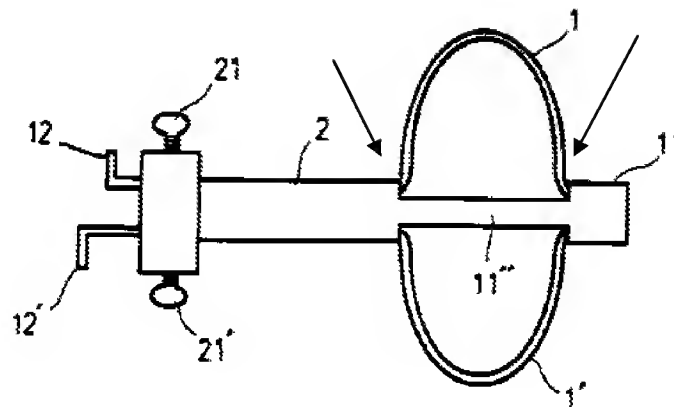
***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 1-5, 8-9, 13-14, 20-23, 26, 31-32, 34-35 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Shaw et al. (US Patent 5,678,572).**

Claim 1, 3, 4, 5, 21, 22, 23, 26: Shaw’572 discloses a medical apparatus having a guide member (2) with a leading end (11) and an aperture (see Figure 4b, area between 1 and 1’) defining an area for access from the apparatus into a body passage. The area is spaced from the leading end (see Figure 4b). The apparatus is controllably movable between a collapse position (Figure 4a) and an expansion position (Figure 4b) by controllably elastically deforming expansion arms (1, 1’). The arms extend across edge regions of the aperture (arrows in the copy of Figure 4b below identify Examiner’s interpretation of edge regions).





Claim 2: Shaw'572 discloses the stay sleeves having a plurality of holes which allows the stays to be incrementally expanded (column 2, lines 23-28).

Claim 8, 9, 26, 42: Shaw'572 discloses an activating device with an activating member (12, 12') adapted for moving the apparatus between the collapsed and expansion positions (column 2, lines 53-55). The activating members are movable relative to guide member 2. They are capable of moving simultaneously.

Claim 13: Shaw'572 discloses screws (21, 21') used to lock the device in a desired position.

Claim 14: Shaw'572 discloses the access area extends from the leading end and part way along a length of the apparatus (see Figure 4b).

Claim 20: Shaw'572 discloses the access area extends around the entirety of the device except for the guide member, which is shown to be less than half of the perimeter of the device (Figure 4b).

Claim 21: Shaw'572 discloses an inlet (Figure 2, inlet near ref. 211) at the trailing end to allow access into the apparatus.

Claim 32: When manually pushing the stay pushers (12) of Shaw'572, an operator of the device would receive force feedback from the stay pusher.

Claims 34 and 35: Shaw'572 discloses inserting a medical apparatus into a body passage in the collapsed position, moving the apparatus into the expansion position by providing an expansion force on the apparatus, controllably elastically deforming expansion arms, and accessing the body passage (column 1, lines 48-62).

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 7, 19, 24-25, 27, 31 and 36-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw'572.**

Claim 6, 7, 36: Shaw'572 discloses the claimed invention except for the arms being at rest in the expanded state, versus being at rest in the unexpanded state or the arms being stressed in the collapsed state and more stressed in the expanded state. It would have been an obvious matter of design choice to make the expanded state the resting position of the arms, since applicant has not disclosed that choosing one state over the other for the resting state solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the resting state being the unexpanded state. Furthermore, if the expanded state were used as a resting state, it would have been obvious to provide a collapse force in the device in

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order to insert it into a body cavity and then release the collapse force to expand the device inside the body cavity.

Claim 19: Shaw'572 fails to specifically disclose the access area having a greater dimension longitudinally than laterally. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the device with an opening that was larger longitudinally than laterally.

Claim 24, 25: Shaw'572 discloses the claimed invention except for shape memory alloy material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use shape memory alloy material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claims 27 and 31: Shaw'572 discloses an alternate embodiment utilizing a soft inflatable tube extending between the leading end and the base of the device which is inflated to move the apparatus to the expansion position (col. 2, lines 57-62). The inflatable tube would be definable as a flexible cover extending between the expansion device and the guide member.

Claim 37: While Shaw'572 fails to specifically disclose the steps of moving the apparatus from the expansion position to the collapse position and removing the apparatus from the body passage, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include such steps in order to avoid leaving a patient with an expanded device still housed within their body.



Claims 38 and 39: While Shaw'572 fails to disclose rotating and re-expanding the device, with or without removing it from the body passage, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide such steps in order to gain access to a desired portion of the patient's body.

Claims 40-41: While Shaw does not specifically disclose viewing the body passage or conducting a diagnostic procedure on the body passage, he does disclose the passage being used for surgical procedures, and it would have been obvious to one of ordinary skill in the art at the time the invention was made to view the passage prior to or during such procedures, and to include diagnostic procedures.

**Claims 10, 12 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw'572 in view of Bonutti (US Patent 5,454,365).**

Claim 10: Shaw'572 does not teach that the dilator is actuated with a screw mechanism.

Bonutti'365 teaches a dilator (Figures 1 and 2) that has an activating device that contains a screw mechanism with a screw threaded member (12) and activating member (16) and movement of the threaded member relative to the activating member adapted to move the apparatus between the expanded and collapsed positions. It would have been obvious to one of ordinary skill in the art to modify the device taught by Shaw'572 with a ratchet mechanism, as taught by Bonutti'365, to controllably expand the dilator.

Claim 12: It is old and well known to motorize movements that were previously controlled by hand.

Claim 33: Shaw'572 does not teach a device for measuring the expansion force.

Bonutti'365 teaches a force measuring device (193; Figure 20) in order to measure the force placed by the expandable portion in order to aid in monitoring and controlling the amount of pressure applied by the expandable portion. It would be obvious to modify device of Shaw'572 with a measuring device, as taught by Bonutti'365, so that it too has this advantage.

**Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw'572 in view of Adams et al. (US Patent 5,325,848).**

Shaw'572 does not teach that the dilator is actuated with a ratchet mechanism.

Adams'848 teaches a dilator (Figure 1) that contains an actuating device (handle 60) including a ratchet mechanism having a slider (100) coupled to the activating member and a locking member (90). Movement of the slider (100) relative to the locking member moves the apparatus between the expanded and collapsed state (Figures 2-4). It would have been obvious to one of ordinary skill in the art to modify the device taught by Shaw'572 with a ratchet mechanism, as taught by Adams'848, to controllably expand the dilator.

Claim 12: It is old and well known to motorize movements that were previously controlled by hand.

**Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw in view of Nobles et al., (US Patent Application 2002/0013601).**

While Shaw'572 fails to disclose a plurality of inflatable elements, Nobles'601 teaches a cavity enlarger apparatus which comprises two annular inflatable chambers

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(104, 106) spaced axially on either side of a central cylindrical access area (Figure 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the inflatable chambers of Nobles in the device of Shaw in order to provide additional securing means to hold the device in place.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LINDSEY BACHMAN whose telephone number is (571)272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. B./

Examiner, Art Unit 3734

/TODD E. MANAHAN/

Supervisory Patent Examiner, Art Unit 3734